UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,297	02/13/2002	Masako Yajima	219451US0	3488

22850 7590 09/29/2006

C. IRVIN MCCLELLAND
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
MOHAMED, ABDEL A	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 09/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/073,297	YAJIMA ET AL.	
	Examiner	Art Unit	
	Abdel A. Mohamed	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 9-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 9-32 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

CONTINUED EXAMINATION UNDER 37 CFR 1.114 AFTER FINAL REJECTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/14/06 has been entered.

ACKNOWLEDGMENT TO AMENDMENT, REMARKS AND STATUS OF THE CLAIMS

2. The amendment and remarks filed 08/14/06 are acknowledged, entered and considered. In view of Applicant's request claims 9, 15, 21 and 27 have been amended. Claims 9-32 are now pending in the application. The rejections under 35 U.S.C. 102(b) and 35 U.S.C. 103(a) over the prior art of record are maintained for the same reasons discussed in the previous Office action.

ARGUMENTS ARE NOT PERSUASIVE

CLAIMS REJECTION-35 U.S.C. § 102(b) AND 35 U.S.C. 103(a)

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9, 15, 21 and 27 remain rejected under 35 U.S.C. 102(b) as being anticipated by Nitsche (U.S. Patent No. 5,240,909).

Claims 10-14, 16-20, 22-26 and 28-32 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Nitsche (U.S. Patent No. 5,240,909).

It is noted that Applicant traversed the rejections of the claims (i.e. claims 9-32) under 35 U.S.C. 102(b) or 35 U.S.C. 103(a) over Nitsche together. Thus, the Examiner responds to Applicant's traversal accordingly.

Applicant's arguments filed 08/14/06 have been fully considered but they are not persuasive. Applicant has argued that Nitsche ('909) patent fails to disclose or suggest the claimed methods. In the *in vivo* tests described in Examples 3 and 4 of Nitsche, bacteria were inoculated before administration of lactoferrin. Nitsche fails to disclose or suggest that **protective** administration of lactoferrin, i.e., prior to bacterial invasion, shows a much better effect as compared to administering lactoferrin after invasion of the bacteria. Accordingly, the claimed method is not disclosed or suggested by that reference is unpersuasive.

Contrary to Applicant's arguments the '909 patent of Nitsche discloses the administration of an effective amount of hLf or animal Lf **as an active agent for suppressing inflammation caused by endotoxin LPS-derived from gram-negative bacteria**. Thus, clearly showing the administration of lactoferrin prior to bacterial invasion to suppress inflammation. In regard to the limitation "**protectively** administering", although, Applicant has not provided support for this limitation of protectively administering, as shown *infra* in the rejection under 35 U.S.C. 112, first paragraph for new matter. Thus, Applicant's argument is directed to a limitation that is not supported in the instant specification.

With respect to Applicant's arguments that the description of lines 61-65 at column 12 reports only that the group to which LF (Lcf-Fe(A)) was administered

showed approximately 58.5% reduction of endotoxin activity as compared to the endotoxin activity in the group to which albumin was administered in place of said Lf. Specifically, albumin was administered intravenously as a control protein in place of hLfin. Nitsche, while it was confirmed by the present inventors that the tested animal's albumin accumulated in the abdominal cavity to which LPS was administered. The description at column 12, lines 61-65 of Nitsche has no relationship with the present invention which albumin accumulation may be alleviated is noted. However, as stated previously the above conditions/situations are natural occurrence due to the inflammation, and as such it is inherent property of lactoferrin administration to alleviate the symptoms of such condition/situation. Furthermore, as acknowledged by Applicant on page 2, paragraph 2 in the instant specification, it is known in the art that during sepsis caused by gram-negative bacilli, decline in blood albumin concentration, decrease of lymphocytic leukocytes, and increase of neutrophil occur. Also, on page 4, Applicant acknowledges that bovine-type lactoferrin has been used to demonstrate an effect of alleviating various symptoms, which appear after infection. Thus, albumin exudation or increase of blood neutrophils at the inflammatory site, these are expected natural occurrence during inflammation whatever the cause of inflammation is. See also the abstract of Jajima et al (The 4th International Conference on Lactoferrin, Program & Abstract, pp. 77, 1999) which states that lactoferrin, in primary defense system against pathogenic invasion, may play a role in the amelioration of phagocytic activity in PMN through the inhibitory action on LPS-induced TNF α production in neonatal rat *in vivo*. Moreover, in view of *In re Sussman*, 141 F. 2d 267, 60 U.S.P.Q.

538 (CCPA 1944), the claims are rejected under 35 U.S.C. 102(b) "that since the steps are the same, the results must inherently be the same unless they are due to conditions not recited in the claims." Applicant is claiming an invention employing the **same process steps** but the product(s) is (are) **alleged to be different**. Applicant is required to recite the missing steps to form the alleged different product(s) in view of the above citation. Thus, the prior art discloses the invention substantially as claimed, and as such, anticipates claims 9, 15, 21 and 27 as drafted and renders claims 10-14, 16-20, 22-26 and 28-32 obvious for the reasons discussed under 35 U.S.C. 103(a) rejection in the previous Office action.

The followings are new grounds of rejections

CLAIMS REJECTION-35 U.S.C. § 112 1st PARAGRAPH

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Independent claims 9, 15, 21 and 27 as amended on 08/14/06 contain new matter because the original specification does not appear to support for the phrase "**protectively** administering...." because the original specification does not have support for the phrase "**protectively**". It is noted that Applicant stated on the remarks filed 08/14/06 that the amendment to claims 9, 15, 21 and 27 are supported by the Examples set forth in the specification, particularly, Example 4 is noted. However, ~~non~~ none of the Examples in the instant specification including Example 4 disclose "A method for alleviating a symptom from lipopolysaccharide-induced inflammation comprising **protectively** administering to a person orally or parenterally an effective amount of human-type lactoferrin for a time and under condition effective to alleviate said symptom", wherein said symptom is accumulation of body fluid containing albumin at the inflammatory site (claim 9); or wherein said symptom is accumulation of albumin at the inflammatory site (claim 15); or wherein said symptom is decrease of albumin concentration in blood (claim 21); or wherein said symptom is increase of neutrophils in blood (claim 27). Thus, independent claims 9, 15, 21, 27 and dependent claims thereof, respectively have no support for "the methods of alleviating a symptom from LPS-induced inflammation comprising **protectively** administering..... "from the original disclosure because there is no disclosure in the specification as now claimed in claims 9-32. Thus, Applicant respectfully requested to either cancel all unsupported subject matter or to show where such subject matter has support from the original disclosure.

CLAIMS REJECTION-35 U.S.C. § 112, SECOND PARAGRAPH

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 9-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9, 15, 21 and 27 are indefinite and confusing in the recitation "protectively administering...."because it is not clear what the term "protectively" encompasses. Is it intended to mean "prevention" or "inhibition" or "therapeutically treating " or "ameliorating". Appropriate clarification is required.

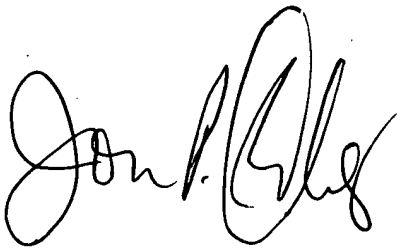
CONCLUSION AND FUTURE CORRESPONDENCE

6. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (571) 272 0955. The examiner can normally be reached on First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tsang Cecilia can be reached on (571) 272 0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



JON WEBER
SUPERVISORY PATENT EXAMINER

AAM Mohamed/AAM
September 23, 2006